REMARKS

Reconsideration and withdrawal of the rejections to the application are respectfully requested in view of the remarks herewith.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 96-124 are now pending. Claims 96-98 have been amended, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that these claims, as originally and herein presented, are and were in full compliance with the requirements of 35 U.S.C. §112. The new claims, as presented herein, are not added for the purpose of patentability within the meaning of 35 U.S.C. §§101, 102, 103 or 112. Rather, these claims are added for clarification and to round out the scope of protection to which Applicants are entitled.

Support for the amended claims is found in the claims as originally presented and throughout the specification.

II. THE ART REJECTIONS ARE OVERCOME

Claims 96-97 and 99-116 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Quelle et al. with evidence provided by Dorland's Illustrated Medical Dictionary and claims 96-116 were rejected under 35 U.S.C. §103(a) as allegedly obvious over Quelle et al. with evidence provided by Dorland's Illustrated Medical Dictionary. The rejections are respectfully traversed and will be addressed collectively. .

Applicants again respectfully assert that Quelle, with or without the evidence provided by Dorland, does not teach or suggest the presently claimed invention; and, Quelle, with or without the evidence provided by Dorland, does not provide any teaching, suggestion, motivation, or incentive to modify the cited document to arrive at the instant invention.

Initially, it is respectfully pointed out that for a Section 102 rejection to stand, the single prior art reference must contain all of the elements of the claimed invention, *see Lewmar Marine Inc. v. Barient Inc.,* 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987), and, the single prior art reference must contain an enabling disclosure, *see Chester v. Miller,* 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990).

It is also well-settled that there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). Further, "obvious to try" is not the standard under 35 U.S.C. §103. *In re Fine,* 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). And, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification." Also, the Examiner is respectfully reminded that for the Section 103 rejection to be proper, both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

Applying the law to the instant facts, it is respectfully submitted that the instant invention is not anticipated or made obvious by Quelle, *inter alia*, because Quelle does not contain a teaching of all of the elements of the instant claims. And, it is respectfully submitted that the instant invention is not rendered obvious by Quelle, as Quelle does not provide a teaching or suggestion of all of the elements of the instant claims, *inter alia*.

The present invention relates to, *inter alia*, a substantially pure, recombinant glycosylated erythropoietin, produced by a baculovirus expression system in cultured insect cells, wherein said erythropoietin has relative homogeneity or is purified to 95% or greater and said erythropoietin stimulates erythropoiesis and has an activity *in vivo* of at least 200,000 U/mg or of about 500,000 U/mg.

Dorland's defines erythropoietin as "a glycoprotein hormone secreted chiefly by the kidney in the adult and by the liver in the fetus, which acts on stem cells of the bone marrow to stimulate red blood cell production (erythropoiesis)." Inherent to this definition is that erythropoiesis is an *in vivo* activity and that erythropoietin acts *in vivo* to cause erythropoiesis.

One element of the claimed invention is that the erythropoietin stimulates erythropoiesis. As discussed above and previously, erythropoietin stimulates erythropoiesis *in vivo*, such that the erythropoietin of the present invention must be active *in vivo*. As such, the *in vivo* activity of the claimed erythropoietin is an element of the claimed present invention.

The Office Action alleges that in the June 25, 2003 Response, Applicants acknowledged that the erythropietin of Quelle has "little activity in vivo." Office Action at 2. Applicants

vigorously deny this allegation, and suggest that the Examiner review page 11 of the June 25, 2003, where Applicants actually **quoted** from page 654 of Quelle that Quelle's erythropoietin had "little, **if any**, activity *in vivo*."

The Office Action states that the present claims do not require *in vivo* activity, and that Applicants have not demonstrated such *in vivo* activity. Office Action at 2-3. The claims as amended herein recite a substantially pure, recombinant glycosylated erythropoietin, produced by a baculovirus expression system in cultured insect cells, wherein said erythropoietin has relative homogeneity or is purified to 95% or greater and said erythropoietin stimulates erythropoiesis and has an activity ***in vivo*** of at least 200,000 U/mg or of about 500,000 U/mg

Further, enclosed herewith is the Declaration of Manon Cox, who declares that under her direction, supervision or control, in the ordinary course of business, the erythropoietin of the present invention was tested and shown to have *in vivo* activity as evidenced by increased reticulocyte counts.

Consequently, it is respectfully asserted that Quelle does not contain all the elements of the present invention as the erythropoietin described in Quelle admittitedly has "little, **if any**, *in vivo* activity". As ***in vivo*** activity is an element of the presently claimed invention, and Quelle's erythropoietin does not possess *in vivo* activity, the rejection under 35 U.S.C. §102(b) is improper and should be withdrawn.

Furthermore, Quelle does not contain any teaching, suggestion, motivation, or incentive to modify which would allow one of skill in the art to arrive at the present invention.

Again, Quelle relates to a purified erythropoietin with "little, **if any**, *in vivo* activity." The present invention relates to, *inter alia*, a purified erythropoietin which stimulates erythropoiesis and has an activity *in vivo* of at least 200,000 U/mg or of about 500,000 U/mg. Accordingly, the erythropoietin of the present invention possesses *in vivo* activity, whereas the erythropoietin described by Quelle does not.

Furthermore, Quelle does not provide any teaching, suggestion, motivation, or incentive to modify the reference in order to obtain a purified erythropoietin which retains its *in vivo* activity. Quelle et al. states that the lack of in vivo activity in their erythropoietin is due to a lack of sialic acid. Further, Quelle et al. states that sialic acid is absent from saccharide structures derived from insects. Quelle at 656. Accordingly, one of skill in the art would expect the present erythropoietin, an insect-cell derived erythropoietin, to lack in vivo activity due to the

absence of sialic acid. However, as shown herein by the accompanying declaration, the present erythropoietin does have *in vivo* activity. Additionally, Quelle does not even suggest the presently claimed invention, i.e. a purified insect cell derived erythropoietin having *in vivo* activity, *inter alia*, or provide any expectation of success in modifying Quelle to arrive at the present invention. Accordingly, the 35 U.S.C. §103(a) rejection is improper and should be withdrawn.

Therefore, because Quelle does not contain all the elements of the presently claimed invention, and because Quelle does not provide any teaching, suggestion, motivation, or incentive to modify to allow one of skill in the art to arrive at the present invention, it is respectfully requested that the rejections under 35 U.S.C. §§ 102(b) and 103(a) be reconsidered and withdrawn.

REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, prior to issuance of any paper other than a Notice of Allowance, an interview, is respectfully requested, with the Examiner his supervisor, and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

The Amendments and remarks herein place the application in condition for allowance. An early and favorable consideration of the application on the merits, and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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